IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

MEDIDEA, L.L.C.,	
Plaintiff,	
V.	C' I'A d' N
MEDACTA USA, INC.,	Civil Action No TRIAL BY JURY DEMANDED
Defendant.	I RIAL DI JURI DEMANDED

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff, MEDIDEA, L.L.C., by its attorneys, hereby complains against Defendant MEDACTA USA, INC. as follows:

I. THE PARTIES

- 1. Plaintiff, MEDIDEA, L.L.C. ("MEDIDEA") is a limited liability company organized and existing under the laws of the State of Michigan.
- 2. Defendant MEDACTA USA, INC. ("MUI") is a corporation organized and existing under the laws of the State of Illinois with a principal place of business located at 1556 West Carroll Ave., Chicago, Illinois 60607. MUI is a subsidiary of Medacta International SA, a company based in Castel San Pietro, Switzerland.
- 3. MUI makes, distributes, sells and/or offers for sale certain knee revision systems, such as, for example, the GMK[®] (Global Medacta Knee) Revision Knee System.
- 4. The GMK® Revision Knee System is indicated for cases of revision of a primary total knee replacement or for primary total knee replacement when bone augmentation is required and/or there is evidence of a moderate collateral ligaments deficiency. Primary total knee arthroplasties may be subject to failure for various reasons, including polyethylene wear,

aseptic loosening, osteolysis, infection, ligamentous instability and patello-femoral complications.

- 5. Federal law restricts the GMK[®] Revision Knee System to sale, by or on the order of a physician and it can be prescribed and implanted only by a doctor legally authorized to perform this type of surgery.
- 6. Each sale of the GMK[®] Revision Knee System is subject to specific "Instructions For Use" ("IFU") distributed by MUI. These "Instructions For Use" are available for download at: https://www.medacta.com/sites/medacta.com/files/documents/instructions for use/IFU_

 KNEE 75.09.030 rev09 0.pdf, a copy of which is attached as Exhibit A.
- 7. The GMK® Revision Knee System's IFU contains the following statement: "Before any surgery, the surgeon must be familiar with the sales product literature and operative technique and must carefully read these instructions for use."
- 8. The GMK® Revision Knee System's IFU contains the following warning: "The success of the operation depends on compliance with the operative technique supplied, and the proper use of the instrumentation supplied and specially designed for that range of implants. The trial instrumentation must be used to confirm the choice of sizes and verify the functionality of the joint."
- 9. The GMK® Revision Knee System's IFU contains the following statement: "The surgeon should be fully familiar with the surgical technique. Supplementary information about the surgical techniques and products are available on request."
- 10. The GMK® Revision Knee System's IFU contains the following statement: "All the implant components of the total knee prosthesis are supplied in single-use individual packages. For components delivered sterile, the sterilization method is indicated on the label."

- 11. The GMK® Revision Knee System's IFU contains the following statement: "Instruments are supplied non-sterile and must be cleaned and sterilized prior to use. Recommended cleaning, decontamination and sterilization instructions are provided on www.medacta.com."
- 12. MUI distributes detailed documentation to surgeons regarding the appropriate operative technique and the proper use of the instrumentation specific to the GMK[®] Revision Knee System. A first one of such documents is entitled: "GMK® Revision System Surgical Technique" and is available for download at: https://www.medacta.com/sites/medacta.com/ files/documents/surgical techniques/TO GMK REVISION SYSTEM US rev00.pdf (Ref. 99. 27S.12US Rev.00), an excerpt of which is attached as Exhibit B. A second one of such documents is entitled "GMK® Revision Surgical Technique" and is available for download at https://www.medacta.com/sites/medacta.com/files/documents/surgical_techniques/ST_GMK_re vision 992712US rev05.pdf (Ref. 99.27. 12US Rev.05), an excerpt of which is attached as Exhibit C. A third one of such documents is entitled "GMK® Revision Trial Components Surgical Technique" and is available for download at: https://www.medacta.com/sites/medacta.com/files/ documents/surgical_techniques/GMKR%20THROUGH%20TRIALS_ENG.pdf (Ref. 99.27.12 TRIALS), a copy of which is attached as Exhibit D. These documents (Ex. B - Ex. D) are collectively referred to herein as the "Surgical Technique Documentation."

II. NATURE OF THE ACTION

- 13. This is an action for patent infringement.
- 14. MUI has infringed and continues to infringe, contribute to the infringement of, and/or actively induces others to infringe MEDIDEA's U.S. Patent No. 5,885,296 ("the '296 Patent"), U.S. Patent No. 5,944,722 ("the '722 Patent"), U.S. Patent No. 5,957,926 ("the '926

Patent"), U.S. Patent No. 6,077,269 ("the '269 Patent"), and U.S. Patent No. 6,102,916 ("the '916 Patent") (collectively "the Patents-in-Suit").

III. JURISDICTION AND VENUE

- 15. This lawsuit is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. §§ 1 et seq. This Court has exclusive subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338.
- 16. This Court has personal jurisdiction over MUI for at least the following reasons: (i) MUI maintains its principal place of business in this District; (ii) MUI has designated an agent for service of process in the State of Illinois; (iii) MUI has committed acts of patent infringement and/or contributed to or induced acts of patent infringement by others in this District and elsewhere in Illinois and the United States; and (iv) MUI regularly does business or solicits business, engages in other persistent courses of conduct, and/or derives substantial revenue from products and/or services provided to individuals in this District and in the state of Illinois.
- 17. Venue properly lies in the Northern District of Illinois pursuant to 28 U.S.C. §§ 1391(b) and (c), and 1400(b) because MUI does business in the state of Illinois, has committed acts of infringement in Illinois and in this District, has a regular and established place of business in this District, and is subject to personal jurisdiction in this District.

IV. CLAIMS

COUNT I – INFRINGEMENT OF THE '296 PATENT

- 18. MEDIDEA realleges and incorporates by reference the allegations set forth in Paragraphs 1-17 of this Complaint as though fully set forth herein.
- 19. MEDIDEA is the owner of all rights, title, and interest in the '296 Patent, entitled "Bone Cutting Guides with Removable Housings for Use in the Implantation of Prosthetic Joint

Components," which was duly and properly issued by the United States Patent and Trademark Office ("USPTO") on March 23, 1998. A copy of the '296 Patent is attached as Exhibit E.

- 20. MEDIDEA is the assignee of the '296 Patent and holds the rights to sue and recover for past, present and future infringement thereof.
- 21. The '296 Patent provides, among other things, the following: a combination trial and bone-cutting guide for use in conjunction with a bone-cutting tool, comprising: (1) a shaped body having an inner surface adapted for temporary placement against a bone surface to be modified and an outer surface having condylar protrusions configured to co-act with a proximal tibia; (2) at least one aperture extending through the body from the outer surface to the inner surface to guide the bone-cutting tool; and (3) a removable housing, the housing extending from a central, intercondylar region including a first end which extends from the inner surface of the body and a second end adapted for penetration into the bone surface.
- 22. Upon information and belief, in violation of 35 U.S.C. § 271, MUI is and has been directly infringing, contributing to the infringement of, and/or inducing others to infringe the '296 Patent by, among other activities, making, using, importing, offering for sale, selling, providing, maintaining and/or supporting, without license or authority, products falling within the scope of one or more claims of the '296 Patent. Such products include, without limitation, certain knee revision systems, such as, for example, the GMK[®] Revision Knee System.
- 23. As a result of MUI's unlawful infringement of the '296 Patent, MEDIDEA has suffered and will continue to suffer damage. Under 35 U.S.C. § 284, MEDIDEA is entitled to recover from MUI the damages suffered by MEDIDEA as a result of its unlawful acts. MUI has committed acts of infringement which have caused damage to MEDIDEA.
- 24. Upon information and belief, MUI intends to continue its unlawful infringing activity, and MEDIDEA continues to and will continue to suffer irreparably harm for which

there is no adequate remedy at law – from such unlawful infringing activities unless this Court enjoins MUI from further infringing activities under 35 U.S.C. § 283.

COUNT II – INFRINGEMENT OF THE '722 PATENT

- 25. MEDIDEA realleges and incorporates by reference the allegations set forth in Paragraphs 1-24 of this Complaint as though fully set forth herein.
- 26. MEDIDEA is the owner of all rights, title, and interest in the '722 Patent, entitled "Bone Cutting Guides for Use in the Implantation of Prosthetic Joint Components," which was duly and properly issued by the USPTO on August 31, 1999. A copy of the '722 Patent is attached as Exhibit F.
- 27. MEDIDEA is the assignee of the '722 Patent and holds the rights to sue and recover for past, present and future infringement thereof.
- 28. The '722 Patent provides, among other things, the following: in knee-replacement surgery, the method of preparing the femur to receive the final implant, comprising the steps of:

 (1) performing a series of box cuts into the end of the femur sufficient to receive the box structure; (2) providing a trial cutting guide having outer condylar surfaces, an intercondylar box structure, and a plurality of bone-modification slots; (3) resecting the bone, if necessary, using the cutting guide; and (4) installing the final implant.
- 29. Upon information and belief, in violation of 35 U.S.C. § 271, MUI is and has been directly infringing, contributing to the infringement of, and/or inducing others to infringe the '722 Patent by, among other activities, making, using, importing, offering for sale, selling, providing, maintaining and/or supporting, without license or authority, products used within the scope of one or more claims of the '722 Patent, and performing or inducing others to perform the steps of one or more claims of the '722 Patent. Such products include, without limitation, certain knee revision systems, such as, for example, the GMK® Revision Knee System and such acts

include supplying the IFU and the Surgical Technique Documentation specific to the GMK[®] Revision Knee System and performing the procedures mandated therein or inducing others to perform the procedures mandated therein.

- 30. As a result of MUI's unlawful infringement of the '722 Patent, MEDIDEA has suffered and will continue to suffer damage. Under 35 U.S.C. § 284, MEDIDEA is entitled to recover from MUI the damages suffered by MEDIDEA as a result of its unlawful acts. MUI has committed acts of infringement which have caused damage to MEDIDEA.
- 31. Upon information and belief, MUI intends to continue its unlawful infringing activity, and MEDIDEA continues to and will continue to suffer irreparably harm for which there is no adequate remedy at law from such unlawful infringing activities unless this Court enjoins MUI from further infringing activities under 35 U.S.C. § 283.

COUNT III – INFRINGEMENT OF THE '926 PATENT

- 32. MEDIDEA realleges and incorporates by reference the allegations set forth in Paragraphs 1-31 of this Complaint as though fully set forth herein.
- 33. MEDIDEA is the owner of all rights, title, and interest in the '926 Patent, entitled "Combination Trial and Bone Cutting Guides for Use in Establishing the Position of a Prosthetic Joint Component," which was duly and properly issued by the USPTO on September 28, 1999. A copy of the '926 Patent is attached as Exhibit G.
- 34. MEDIDEA is the assignee of the '926 Patent and holds the rights to sue and recover for past, present and future infringement thereof.
- 35. The '926 Patent provides, among other things, the following: in joint-replacement arthroplasty, a method of shaping a bone to establish the position of a final prosthetic component, comprising the steps of: (1) providing a combination trial and cutting guide; (2) modifying the bone, if necessary, to receive the combination trial and cutting guide; (3)

performing a trial joint reduction with the combination trial and cutting guide in place; and (4) upon achieving a successful trial joint reduction, resecting the bone using the combination trial and cutting guide to establish the position of the final prosthetic component.

- 36. Upon information and belief, in violation of 35 U.S.C. § 271, MUI is and has been directly infringing, contributing to the infringement of, and/or inducing others to infringe the '926 Patent by, among other activities, making, using, importing, offering for sale, selling, providing, maintaining and/or supporting, without license or authority, products used within the scope of one or more claims of the '926 Patent, and performing or inducing others to perform the steps of one or more claims of the '926 Patent. Such products include, without limitation, certain knee revision systems, such as, for example, the GMK® Revision Knee System and such acts include supplying the IFU and the Surgical Technique Documentation specific to the GMK® Revision Knee System and performing the procedures mandated therein or inducing others to perform the procedures mandated therein.
- 37. As a result of MUI's unlawful infringement of the '926 Patent, MEDIDEA has suffered and will continue to suffer damage. Under 35 U.S.C. § 284, MEDIDEA is entitled to recover from MUI the damages suffered by MEDIDEA as a result of its unlawful acts. MUI has committed acts of infringement which have caused damage to MEDIDEA.
- 38. Upon information and belief, MUI intends to continue its unlawful infringing activity, and MEDIDEA continues to and will continue to suffer irreparably harm for which there is no adequate remedy at law from such unlawful infringing activities unless this Court enjoins MUI from further infringing activities under 35 U.S.C. § 283.

COUNT IV – INFRINGEMENT OF THE '269 PATENT

39. MEDIDEA realleges and incorporates by reference the allegations set forth in Paragraphs 1-38 of this Complaint as though fully set forth herein.

- 40. MEDIDEA is the owner of all rights, title, and interest in the '269 Patent, entitled "Bone Cutting Guides with Centralized Recesses for Use in the Implantation of Prosthetic Joint Components," which was duly and properly issued by the USPTO on June 20, 2000. A copy of the '269 Patent is attached as Exhibit H.
- 41. MEDIDEA is the assignee of the '269 Patent and holds the rights to sue and recover for past, present and future infringement thereof.
- 42. The '269 Patent provides, among other things, the following: a combination trial and cutting guide which facilitates a trial joint reduction in conjunction with a tibial spacer having a superior protrusion, the combination trial and cutting guide comprising: (1) a solid body having an anterior portion, a posterior portion, an inner surface adapted for temporary placement against a bone to be modified, and an outer, articulating surface including a pair of medial and lateral condylar protrusions, each having a smooth curved convex surface extending from the anterior portion to the posterior portion of the body to interact with a corresponding tibial articular surface; (2) one or more bone-modification slots extending through the body; and (3) a passageway formed in a central region of the body, the passageway extending from the anterior portion to the posterior portion of the body so as to accommodate the superior protrusion of the tibial spacer during the trial joint reduction, thereby enabling the knee to be tested in flexion and extension with the post received within the passageway.
- 43. Upon information and belief, in violation of 35 U.S.C. § 271, MUI is and has been directly infringing, contributing to the infringement of, and/or inducing others to infringe the '269 Patent by, among other activities, making, using, importing, offering for sale, selling, providing, maintaining and/or supporting, without license or authority, products falling within the scope of one or more claims of the '269 Patent. Such products include, without limitation, certain knee revision systems, such as, for example, the GMK[®] Revision Knee System.

- 44. As a result of MUI's unlawful infringement of the '269 Patent, MEDIDEA has suffered and will continue to suffer damage. Under 35 U.S.C. § 284, MEDIDEA is entitled to recover from MUI the damages suffered by MEDIDEA as a result of its unlawful acts. MUI has committed acts of infringement which have caused damage to MEDIDEA.
- 45. Upon information and belief, MUI intends to continue its unlawful infringing activity, and MEDIDEA continues to and will continue to suffer irreparably harm for which there is no adequate remedy at law from such unlawful infringing activities unless this Court enjoins MUI from further infringing activities under 35 U.S.C. § 283.

COUNT V – INFRINGEMENT OF THE '916 PATENT

- 46. MEDIDEA realleges and incorporates by reference the allegations set forth in Paragraphs 1-45 of this Complaint as though fully set forth herein.
- 47. MEDIDEA is the owner of all rights, title, and interest in the '916 Patent, entitled "Bone Cutting Guides with Removable Housings for Use in the Implantation of Prosthetic Joint Components," which was duly and properly issued by the USPTO on August 15, 2000. A copy of the '916 Patent is attached as Exhibit I.
- 48. MEDIDEA is the assignee of the '916 Patent and holds the rights to sue and recover for past, present and future infringement thereof.
- 49. The '916 Patent provides, among other things, the following: a combination trial and bone-cutting guide for use in conjunction with a bone-cutting tool, comprising: (1) a shaped body having an inner surface adapted for temporary placement against a bone surface and an outer surface having medial and lateral condyles configured to co-act with a proximal tibia; (2) at least one slot extending through the body from the outer surface to the inner surface to guide the bone-cutting tool; and (3) a housing removably attached to a central, intercondylar region of the body, the housing including a box structure extending from the inner surface of the body

penetrable at least partially into the bone surface and a distally oriented recess to receive a tibial protrusion of the type associated with the cruciate-sacrificing procedures.

- 50. Upon information and belief, in violation of 35 U.S.C. § 271, MUI is and has been directly infringing, contributing to the infringement of, and/or inducing others to infringe the '916 Patent by, among other activities, making, using, importing, offering for sale, selling, providing, maintaining and/or supporting, without license or authority, products falling within the scope of one or more claims of the '916 Patent. Such products include, without limitation, certain knee revision systems, such as, for example, the GMK[®] Revision Knee System.
- 51. As a result of MUI's unlawful infringement of the '916 Patent, MEDIDEA has suffered and will continue to suffer damage. Under 35 U.S.C. § 284, MEDIDEA is entitled to recover from MUI the damages suffered by MEDIDEA as a result of its unlawful acts. MUI has committed acts of infringement which have caused damage to MEDIDEA.
- 52. Upon information and belief, MUI intends to continue its unlawful infringing activity, and MEDIDEA continues to and will continue to suffer irreparably harm for which there is no adequate remedy at law from such unlawful infringing activities unless this Court enjoins MUI from further infringing activities under 35 U.S.C. § 283.

V. PRAYER FOR RELIEF

WHEREFORE, MEDIDEA prays for the following relief:

- (a) That the Patents-in-Suit be declared good and valid in law;
- (b) That MUI be declared to have infringed, induced others to infringe and/or committed acts of contributory infringement with respect to the claims of the Patents-in-Suit, as alleged above;
- (c) That MUI and its officers, agents, servants, employees, and all those persons acting or attempting to act in active concert or in participation with them or

- acting on their behalf be permanently enjoined under 35 U.S.C. § 283 from further infringement of the Patents-in-Suit;
- (d) That MUI be ordered to account for and pay to MEDIDEA all damages caused to MEDIDEA by reason of MUI's infringement of the Patents-in-Suit pursuant to 35 U.S.C. § 284;
- (e) That MEDIDEA be granted such other and additional relief as the Court deems just and proper.

VI. <u>DEMAND FOR JURY TRIAL</u>

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff MEDIDEA hereby demands a trial by jury as to all issues so triable.

Dated: August 14, 2014 Respectfully submitted,

/s/ Jeffrey R. Moran

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